

PATENT COOPERATION TREATY

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

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PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year) 14 MAR 2005

Applicant's or agent's file reference
512520 NJC

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/NZ2004/000315

International filing date (day/month/year)
6 December 2004

Priority date (day/month/year)
8 December 2003

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. ⁷ A61M 16/00, 16/06

Applicant

FISHER & PAYKEL HEALTHCARE LIMITED et al

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the IPEA/AU

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/NZ2004/000315

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/NZ2004/000315

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:
- ☒ paid additional fees
 - ☐ paid additional fees under protest
 - ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1-7 are directed to a cushion for a patient interface. It is considered that the cushion cover and the cushion body being of the same elemental material comprise a first "special technical feature".
2. Claims 8-10 are directed to a cushion for a patient interface. It is considered that the cushion body being detachable from the outer sheath and the patient interface comprises a second "special technical feature".
3. Claims 11-14 are directed to a mask. It is considered that the plurality of adjacent voids comprises a third "special technical feature".

Since the above mentioned groups of claims do not share any of the technical features identified, a "technical relationship" between the inventions, as defined in PCT rule 13.2 does not exist. Accordingly the international application does not relate to one invention or to a single inventive concept, a priori.

It is considered that search and examination for the second and the third inventions will require more than a little additional search and examination effort over that for the first invention, and therefore additional search fees are warranted.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

- ☒ all parts
- ☐ the parts relating to claims Nos.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/NZ2004/000315

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 8-16	YES
	Claims 1-7	NO
Inventive step (IS)	Claims 8-16	YES
	Claims 1-7	NO
Industrial applicability (IA)	Claims 1-16	YES
	Claims	NO

2. Citations and explanations:**NOVELTY:****Claims 1-7:**

- ♦ US 2003/0196658 A1
- ♦ WO 1998/004310 A1
- ♦ EP 1258266 A1
- ♦ EP 0427474 A2
- ♦ US 5441046 A
- ♦ WO 2001/097893 A1

The claimed invention lacks novelty in view of a large number of documents. The art is replete with suggestions and disclosures of a cushion for a patient interface adapted to supply gas to a patient as presently defined. The above documents are provided as examples chosen from many in a well traversed art.

For example EP 0427474 A2 discloses a cushion for a patient interface adapted to supply gas to a patient comprising a cushion body and an outer cover, wherein said body and cover are of the same elemental material.

Claims 8-10:

None of the documents cited in the Search Report disclose a cushion for a patient interface adapted to supply gas to a patient comprising a cushion body having an outer cover, and an outer sealing sheath, wherein the cushion body is detachable from the outer sheath and the patient interface.

Claims 11-16:

None of the documents cited in the Search Report disclose a mask adapted to deliver gas to a patient comprising a cushion body wherein at least a portion thereof has a plurality of adjacent voids.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International Application No.

PCT/NZ2004/000315

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box No. V

INVENTIVE STEP (IS):

Claims 1-7:

Because the subject matter of all the claims is totally disclosed by the documents cited under "novelty", the subject matter is considered to be obvious in view of those documents.

Claims 8-10:

The subject matter of these claims is not rendered obvious in view of the teachings of any prior art documents taken in combination or in combination with common general knowledge.

Claims 11-16:

The subject matter of these claims is not rendered obvious in view of the teachings of any prior art documents taken in combination or in combination with common general knowledge.

INDUSTRIAL APPLICATION:

The claims define subject matter that would be suitable for industrial application.

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International application No.

PCT/NZ2004/000315**Box No. VI Certain documents cited****1. Certain published documents (Rules 43bis.1 and 70.10)**

<u>Application No. Patent No.</u>	<u>Publication date (day/month/year)</u>	<u>Filing date (day/month/year)</u>	<u>Priority date (valid claim) (day/month/year)</u>
WO 2004/007010 A1 (P,X)	22 January 2004	11 July 2003	12 July 2002

With regard to the document(s) listed in Box VI under "certain documents cited", these are documents published prior to the international filing date but later than the priority date claimed but which would otherwise be considered to be of particular relevance.

Under the PCT, novelty is considered only in respect of documents published before the priority date. The relevance of a document published after the priority date is dependent upon national law. Such documents are excluded from consideration in preliminary examination, under the PCT Guidelines but have been included here for information.

2. Non-written disclosures (Rules 43bis.1 and 70.9)

<u>Kind of non-written disclosure</u>	<u>Date of non-written disclosure (day/month/year)</u>	<u>Date of written disclosure referring to non-written disclosure (day/month/year)</u>